



MassBiologics

10-5-16

Medicine for Better Lives



October 1, 2016

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PM

Honorable Steven T. James
Clerk of the House of Representatives
Room 145
State House
Boston, MA 02133

Honorable William F. Welch
Clerk of the Senate
Room 335
State House
Boston, MA 02133

Dear Mr. James and Mr. Welch:

As required by Chapter 75, Section 43(f), we are pleased to "submit to the Clerks of the Senate and the House of Representatives, a report of the activities of Mass Biologics within ninety days after the end of the fiscal year." This is the twentieth year of such annual reports required by the legislation, which transferred MassBiologics from the Department of Public Health to the University of Massachusetts.

If you have any questions, please contact John Finch, MassBiologics, 460 Walk Hill St., Boston, MA 02126, (617) 474-3251.

Sincerely,

Michael F. Collins, M.D.
Chancellor
University of Massachusetts Medical School

Mark S. Klempner, M.D.
Executive Vice Chancellor, MassBiologics
University of Massachusetts Medical School

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**A REPORT OF THE ACTIVITIES OF MASSBIOLOGICS
FISCAL YEAR 2016**

AS REQUIRED BY CHAPTER 75, SECTION 43(F)

**SUBMITTED TO
CLERK OF THE HOUSE OF REPRESENTATIVES**

&

CLERK OF THE SENATE

October 1, 2016

BY

**MASSBIOLOGICS of the
UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL**

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I. INTRODUCTION

This report is submitted, as required by Chapter 75, Section 43(f), on the activities of the MassBiologics of the University of Massachusetts Medical School. This is the twentieth year of such annual report.

The following sections provide the required information as follows:

Part 2, Prior Fiscal Year (FY16) Information, as indicated by legislation, describes the patents and licenses, agreements entered into, status of existing agreements, royalties and other benefits, and expenditures, current assets and liabilities. This section includes two schedules: (1) FY16 Balance Sheet and (2) FY16 Statement of Revenues and Expenditures and Other Charges. Included here is information related to appropriated funds for the prior fiscal year, as required by the legislation.

Part 3, Financial Plans, presents projected revenues and expenses. A three-year projection is included.

2. PRIOR FISCAL YEAR (FY16) INFORMATION

This section of the report presents the specific information indicated in the legislation related to the prior fiscal year (FY16: July 1, 2015 - June 30, 2016). This is the twentieth full year in which MassBiologics has operated within the University of Massachusetts. The effective date of the transfer to the University of Massachusetts was January 1, 1997.

a. Patents and Licensing

MassBiologics has had two patents with claims allowed in FY16:

Antibodies Against Clostridium Difficile Toxins and Uses Thereof

- 1) 12/22/2015 United States Patent No. 9217029
- 2) 4/29/2016 India Patent No. 4482/CHENP/2010

b. Agreements entered into

MassBiologics extended its exclusive distribution agreement with Grifols Worldwide Operations Ltd. for the distribution of Tetanus and Diphtheria vaccine for a one year term ending June 30, 2017.

MassBiologics entered into a series of research and collaboration agreements as follows:

- 1) Antagen Pharmaceuticals Inc., for the development of a diphtheria antibody effective 10/15/2015.
- 2) AbCellera Biologics Inc., to discover human antibodies against drug resistant bacteria effective 3/14/2016.
- 3) Saureus Inc. for evaluation of a diagnostic for C. Difficile infection effective 4/12/2016.
- 4) University of Pennsylvania for plasmids to in AAV vector research effective 5/13/2016.

MassBiologics signed Service Agreements with 6 new clients (client names withheld per non-disclosure agreements) and secured repeat business from 4 existing clients, executed 56 work order agreements that will generate \$16,401,000 in new revenue, while continuing to build a pipeline of new potential customers for contract manufacturing services. MassBiologics South Coast Vector Manufacturing Center completed renovations to GMP manufacturing suites without interrupting its ability to execute client nonGMP development projects.

c. Grants and Contracts Awarded

DARPA Award of \$11,411,276 was received from Defense ADV Research Projects Agency effective July 1, 2013 through May 30, 2017. - \$3,076,990 of funding was received in FY16.

R24 Grant - A no cost extension was received on Award of \$1,332,331 - from National Institutes of Health through January 31, 2016. - An additional Award of \$684,206 was received effective January 1, 2016 through November 30, 2019. \$265,914 of funding was received in FY16.

NIH Contract - Award of \$5,378,361 was received from NIH-Nat'l Inst. of Allergy & Infectious Disease effective September 29, 2013 through September 28, 2016. - \$1,806,876 of funding was received in FY16.

NIH Grant Award of \$1,160,228 was received from NIH-Nat'l Inst. of Allergy & Infectious Disease effective May 1, 2014 through April 30, 2017. - \$351,788 of funding was received in FY16.

MLSC Grant Award of \$5,000,000 was received from Massachusetts Life Sciences Center effective July 1, 2014 through June 30, 2016. \$1,790,718 of funding was received in FY16.

EOHED Grant Award of \$5,000,000 was received from MassWorks Infrastructure Program effective December 10, 2014 through June 30, 2016. \$4,045,258 of funding was received in FY16.

NIH Grant Award of \$89,827 was received from NIH-Nat'l Ctr Advancing Transitional Sciences effective April 1, 2014 through September 30, 2015 with a no cost extension through June 30, 2016. \$2,387 of funding was received in FY16.

NIH Grant Award of \$103,163 was received from NIH-Nat'l Inst. of Neurological Disorders and Stroke effective September 20, 2015 through August 31, 2017. \$74,526 of funding was received in FY16.

CDC Contract - Award of \$190,260 was received from Antigen Pharmaceuticals, Inc. effective September 30, 2015 through September 29, 2017. \$36,298 of funding was received in FY16.

d. Status of existing agreements, royalties and other benefits

MassBiologics had the following major existing agreements in FY16.

Bristol-Meyers Squibb, formerly Medarex - a collaborative development agreement had previously been signed April 17, 2002 with a public company (Medarex). This agreement remains in place in support of MassBiologics' continued research.

The Materials Cooperative Research and Development Agreement (M-CRADA) that was entered into January 30, 2004 with the CDC for Rabies was extended until January 30, 2006. Subsequently, that agreement evolved into an Inter-institutional Agreement that was executed in August 2005.

Merck Exclusive License Agreement April 20, 2009 for antibodies against *C. Difficile*. This agreement remains in place in support of continued clinical development of MassBiologics' proprietary CDiff antibodies.

Serum Institute of India License and Collaboration Agreement effective September 27, 2006. This agreement remains in effect for the development and commercialization of a rabies monoclonal antibody for the treatment of rabies.

Grifols Inc. Research Collaboration and License effective 5/17/2014 for the development of a rabies monoclonal antibody therapeutic in North America.

Grifols Inc. Distribution Agreement for Td vaccine in USA and Canada, effective 7/1/2015.

Voyager Therapeutics Inc. Strategic Collaboration Agreement for development and manufacturing of adeno associated virus (AAV) products, effective 10/20/2014.

Life Technologies Corporation – Cell Line Services License agreement effective 12/19/2014; Commercial Production License effective 5/1/2015; authorizes use of certain materials to support internal research and for use in services provided to external parties.

Sale of Reagents: Reagents are by-products of the major manufacturing products of MassBiologics. MassBiologics makes these reagents available for research purposes.

e. Revenues, expenditures, assets and liabilities

On the pages that follow, please find two schedules: (1) FY16 Statement of Revenues and Expenditures and Other Charges, and (2) FY16 Balance Sheet. This information is reviewed as part of the University of Massachusetts annual audit and is included as part of comprehensive financial reports made to the University of Massachusetts' Board of Trustees. Financial activities are also reported to the Office of the State Comptroller.

When reviewing these schedules, please note:

- State Appropriations / DPH represents the DPH appropriated fund support of the effort at the Biologic Laboratories of \$668,409. These funds only partially support staff and provide the supplies and equipment used in the production of vaccine which is distributed to residents of Massachusetts without charge. The vaccine that is provided is Tetanus-Diphtheria vaccine (Td).
- License and Royalty Fees represents such payments received for CMV-IGIV, and monoclonal antibodies to RSV and *C difficile*.

The Plant Fund is to cover the replacement of major equipment, essential facility improvements necessary to meet FDA and other manufacturing license requirements. This account includes the cumulative capitalized equipment purchases and building improvements and a balance of unexpended funds in reserve for planned equipment purchases and building improvements. In FY16, the plant fund continued to also be used to conclude the new facility expenses.

The core activities of MassBiologics remained consistent through FY16. By way of review, in calendar year 2008, the MassBiologics received its licensure from the FDA to bring its new production facility on line. MassBiologics continued to manufacture clinical material in the new production facility to support its IND activities.

The new production facility is located at the old Boston State Hospital location. This location was authorized by the legislature in July 2000 and opened October 2005. To support the costs of the new facility, Worcester City Campus Corporation borrowed in FY02 in reliance on its lease with the University of Massachusetts Medical School acting on behalf of MassBiologics. The plant fund represents payment of the lease payments supporting the bonds, as well as other capital costs associated with Worcester City Campus Corporation, the University of Massachusetts Medical School and the capital needs and operations of MassBiologics.

Construction of Mattapan II was completed in the late spring of 2010. The project was on time and within budget. Mattapan II was also occupied in this timeframe.

To support the costs of Mattapan II, Worcester City Campus Corporation borrowed \$35 million in FY 07 in reliance on its lease with the University of Massachusetts Medical School acting on behalf of the MassBiologics.

It was determined that MassBiologics would benefit from consolidating its operations to one campus by making facilities modifications to the Mattapan Campus. Modifications completed by June 2013 made it possible for MassBiologics to leave the Jamaica Plain Campus effective June 30, ending a 119 year tenancy at that campus. Commissioning and validation activities have been completed and the FDA has inspected and approved the manufacturing of Td vaccine.

In fiscal 2015 it was determined that the MAB facility developed under the guidance of the UMass Dartmouth campus would be a better strategic fit if it were configured as a cGMP manufacturing resource for the development of vectored therapeutics under the operational control of MassBiologics. The previously identified grants totaling \$10M from the MLSC and MassWorks were invested in the facility located at 1240 Innovation Way to support the cGMP requirements of vector manufacturing. In fiscal year 2016, the initial scope of work was completed on time and on budget with a few areas identified for future projects. The facility is now positioned to develop and manufacture cGMP requirements of vector manufacturing and continue to undergo the process to become validated.

MassBiologics received a \$2M business loan from the Greater Fall River Development in fiscal year 2016. Payments will be repaid over the next five years.

University of Massachusetts Biologic Laboratories
Statement of Revenues, Expenditures and Other Changes
For the Period July 1, 2015 Through June 30, 2016

(Unaudited)

	CURRENT FUND	APPROPRIATED FUNDS	TOTAL
REVENUE AND OTHER ADDITIONS:			
Product Sales	24,829,093		24,829,093
Restricted Grants & Contracts	11,450,755		11,450,755
State Appropriations/DPH		668,409	668,409
Royalty Fees and Interest	15,134,793		15,134,793
Recovery of Indirect Costs	641,977		641,977
Other Income	721,771		721,771
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Total Revenue and Other Additions	52,778,389	668,409	53,446,798
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EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	18,723,153	400,191	19,123,344
Fringe Benefits	5,508,057	108,652	5,616,709
Supplies and Services	29,142,749	159,566	29,302,315
Depreciation	2,104,803		2,104,803
	<hr/>		
Total Expenditures and Other Deductions	55,478,762	668,409	56,147,171
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Net Increase/(Decrease) Before Transfers	(2,700,373)		(2,700,373)
Nonmandatory Transfers			
Transfers	(20,600,000)		(20,600,000)
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Total Transfers	(20,600,000)	0	(20,600,000)
<hr/>			
Other Changes			
Excess of Restricted Receipts over Transfers to Revenue			
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NET INCREASE(DECREASE) FOR THE YEAR	(23,300,373)		(23,300,373)
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Fund Balances at Beginning of Year (7/1/15)	63,898,007		63,898,007
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FUND BALANCES AT END OF YEAR	40,597,634	0	40,597,634
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University of Massachusetts Biologic Laboratories

Balance Sheet

As of June 30, 2016

(Unaudited)

	CURRENT FUND FY16	PLANT FUND FY16	TOTAL FY16
Assets			
Cash	7,358,366	3,090,776	10,449,142
Accounts Receivable	13,186,719		13,186,719
Inventory	8,604,658		8,604,658
Prepaid Expenses	121,121	8,645	129,766
Buildings & Equipment		12,525,518	12,525,518
Other Assets			
Total Assets	29,270,864	15,624,939	44,895,803
Liabilities			
Accounts Payable	1,241,335		1,241,335
Employee-Related Accruals	981,834		981,834
Other Liabilities	75,000	2,000,000	2,075,000
Total Liabilities	2,298,169	2,000,000	4,298,169
Fund Balances	26,972,695	13,624,939	40,597,634
Total Liabilities and Fund Balance	29,270,864	15,624,939	44,895,803

Financial Plans

University of Massachusetts Biologic Laboratories
Statement of Revenues, Expenditures and Other Changes
For the Period July 1, 2016 Through June 30, 2017

(Unaudited)

	CURRENT FUND	APPROPRIATED FUNDS	TOTAL
REVENUE AND OTHER ADDITIONS:			
Product Sales	29,561,927		29,561,927
Restricted Grants & Contracts	5,744,687		5,744,687
State Appropriations/DPH		797,711	797,711
Royalty Fees and Interest	18,220,388		18,220,388
Recovery of Indirect Costs	822,032		822,032
Other Income	1,255,210		1,255,210
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Total Revenue and Other Additions	55,604,244	797,711	56,401,955
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EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	19,558,892	405,732	19,964,624
Fringe Benefits	6,242,777	129,834	6,372,611
Supplies and Services	26,439,404	262,145	26,701,549
Depreciation	2,560,307		2,560,307
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Total Expenditures and Other Deductions	54,801,380	797,711	55,599,091
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Net Increase/(Decrease) Before Transfers	802,864		802,864
Nonmandatory Transfers			
Transfers			
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Total Transfers	0	0	0
<hr/>			
Other Changes			
Excess of Restricted Receipts over Transfers to Revenue			
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NET INCREASE(DECREASE) FOR THE YEAR	802,864		802,864
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Fund Balances at Beginning of Year (7/1/16)	40,597,634		40,597,634
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FUND BALANCES AT END OF YEAR	41,400,498		41,400,498
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University of Massachusetts Biologic Laboratories
Statement of Revenues, Expenditures and Other Changes
For the Period July 1, 2017 Through June 30, 2018

(Unaudited)

	<u>CURRENT</u> <u>FUND</u>	<u>APPROPRIATED</u> <u>FUNDS</u>	<u>TOTAL</u>
REVENUE AND OTHER ADDITIONS:			
Product Sales	32,905,350		32,905,350
Restricted Grants & Contracts	5,513,922		5,513,922
State Appropriations/DPH		540,566	540,566
Royalty Fees and Interest	19,084,138		19,084,138
Recovery of Indirect Costs	652,876		652,876
Other Income	755,210		755,210
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Total Revenue and Other Additions	<u>58,891,496</u>	<u>540,566</u>	<u>59,432,062</u>
EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	20,860,860	405,732	21,266,592
Fringe Benefits	6,660,148	129,834	6,789,982
Supplies and Services	25,429,077	5,000	25,434,077
Depreciation	2,834,691		2,834,691
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Total Expenditures and Other Deductions	<u>55,784,776</u>	<u>540,566</u>	<u>56,325,342</u>
Net Increase/(Decrease) Before Transfers	3,106,720		3,106,720
Nonmandatory Transfers			
Transfers			
Total Transfers	<u>0</u>	<u>0</u>	<u>0</u>
Other Changes			
Excess of Restricted Receipts over Transfers to Revenue			
NET INCREASE(DECREASE) FOR THE YEAR	3,106,720		3,106,720
Fund Balances at Beginning of Year (7/1/17)	<u>41,400,498</u>		<u>41,400,498</u>
FUND BALANCES AT END OF YEAR	<u>44,507,218</u>	<u>0</u>	<u>44,507,218</u>

University of Massachusetts Biologic Laboratories
Statement of Revenues, Expenditures and Other Changes
For the Period July 1, 2018 Through June 30, 2019

(Unaudited)

	<u>CURRENT</u> <u>FUND</u>	<u>APPROPRIATED</u> <u>FUNDS</u>	<u>TOTAL</u>
REVENUE AND OTHER ADDITIONS:			
Product Sales	36,466,360		36,466,360
Restricted Grants & Contracts	4,551,727		4,551,727
State Appropriations/DPH		540,566	540,566
Royalty Fees and Interest	20,189,138		20,189,138
Recovery of Indirect Costs	482,251		482,251
Other Income	755,210		755,210
Total Revenue and Other Additions	<u>62,444,686</u>	<u>540,566</u>	<u>62,985,252</u>
 EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	22,681,848	405,732	23,087,580
Fringe Benefits	7,239,615	129,834	7,369,449
Supplies and Services	26,526,438	5,000	26,531,438
Depreciation	3,112,587		3,112,587
Total Expenditures and Other Deductions	<u>59,560,488</u>	<u>540,566</u>	<u>60,101,054</u>
Net Increase/(Decrease) Before Transfers	<u>2,884,198</u>		<u>2,884,198</u>
 Nonmandatory Transfers			
Transfers			
Total Transfers	<u>0</u>	<u>0</u>	<u>0</u>
 Other Changes			
Excess of Restricted Receipts over Transfers to Revenue			
NET INCREASE(DECREASE) FOR THE YEAR	<u>2,884,198</u>		<u>2,884,198</u>
Fund Balances at Beginning of Year (7/1/18)	<u>44,507,218</u>		<u>44,507,218</u>
FUND BALANCES AT END OF YEAR	<u>47,391,416</u>	<u>0</u>	<u>47,391,416</u>